

Patent application**SURGICAL DRAPE**

5

[Description and technical state of the art]

10 The invention concerns a surgical drape, in particular for surgery of the head.

Surgical drapes serve to keep the area of the surgical incision site as clean and sterile as possible. Most of the drapes feature in their main sheet, for that purpose, 15 apertures formed according to the incision site, so called "fenestrations", or these are correspondingly cut. Within the fenestration, so-called "incise drapes or foils" are then adhered. Such drapes can be obtained from several producers already assembled with pre-cut incise films inserted in 20 standardized dimensions.

After the skin of the patient has been cleaned and disinfected in the incision site, the incise film is usually adhered to the skin in the area of the surgical incision site and allows - since the films are usually transparent - direct 25 intervisibility with the border area of the surgical incision site as well. For fixation, the incise films feature special bonding surfaces, which are usually covered by removable protection films.

In the state of art, several such drapes, including "incise 30 drapes or films" are known.

For example, DE 26 02 562 A1 (based on US application number 545 288) and DE 26 02 563 A1 (based on US application

number 545 289) (from applicant Johnson & Johnson and a priority date of 1/29/1975) show, respectively, a surgical drape consisting of a main sheet, comprised of a flexible, adaptable material, a collar fastened to the upper area of the main sheet with hands-receiving pockets, and an adhesive strip in order to attach the drape in a removable manner to the body (in particular the head) of the patient. Both of the aforementioned drapes feature several complex fold lines. Both serve the purpose of shortening the preparation time of an operation and ensuring sterile coverage.

US 37 91 382, quoted in DE 29 15 627 C2 (Johnson & Johnson, application date 4/18/79), features pouches for receiving fluids which typically occur during a cranial operation which are located on the surface of such a drape in the area which hangs under the operating table. DE 29 15 627 C2 offers an improvement in the form of specially formed cloths which should ensure that fluids which possibly occur are in fact securely lead to such a pouch.

A newer document (US 6 129 085, as a divisional application of Ser. N° 08/705,689 applied on 8/30/1996, US Pat. N° 5 778 889, Kimberly-Clark) likewise proposes a surgical drape ("craniotomy drape" corresponds to "cranial opening drape", in particular for an operation on the cranium. The drape presented in that patent should allow the anesthetist eye-contact with the face of the patient at all times throughout the operation; furthermore, the drape should not trail on the floor of the operating room; finally, the drape should feature easily adjustable and weight-bearing clamps for the attachment of instruments, tubes, etc. During the execution of all tasks the sterility of the room in the area of the patient should remain maintained. The aforementioned US 5 778 889 proposes, to solve this task, a craniotomy drape with a run-off collection pouch below the head area of the patient to be operated on whereby the drape features on the sides of

the main sheet a "gusset" or a "corner drape" as well as lateral, flat and transparent parts in one embodiment. Both parts (the gusset and the transparent lateral parts) are measured in such a way that they prevent the drape from
5 reaching the floor (depending on the height of the operating table). The drape features further in another embodiment holders for receiving instruments, or cables and tubes respectively.

DE 195 10 020 A1 (General Electric, application date
10 3/29/94 from US 2 195 79) proposes a drape which contains a coil between two layers to enable MRI imaging to be performed during operations.

Publications which deal directly or almost exclusively with "incise sheets" or films, etc. are, e.g.:

15 CA 2 314 962 (application date 01/08/1999) proposes a special point- and ring-shaped arrangement of the adhesive surfaces.

US 5 979 450 (applicant 3M, application date 4/9/1998) provides for an incise or pre-cut film or drape which is
20 reinforced by the use of covering sheets and, if necessary, additional tensioning strips ("liners") in order to be able to fasten the incise film in a wrinkle-free state on the body of the patient.

EP 0 902 660 B1 (applicant 3M, priority date as indicated
25 in the US priority-certificates serial no 08/648,903 and 08/724,744, the earliest on 05/16/1996) proposes, for the same purpose, an incise film without covering sheets (liners) which can be unrolled.

EP 0 568 401 B1 (applicant Laboratoire Hydrex (SA), FR,
30 application date with priority of FR 92 052 50, 04/29/92) proposes, for the same purpose of " wrinkle-free fastening capacity", a (such as EP 0 902 660 B1) three-layer incise film as well, however one which features a covering sheet for the reinforcement of the transparent lamination on the other

side and in addition to that a perforation which extends through all three layers.

Due to further development within surgery, the exact location of the surgical incision site is measured 2- or 3-dimensionally in the time before the incision (e.g. by MRI, MRT, x-ray or ultrasound) in order to localize the area as precisely as possible and with that, e.g. to protect healthy tissue as much as possible.

After this "determination", the surgical incision occurs in the operating room, whereby other or further 3-dimensional measurement systems, e.g. so-called navigation systems, which work, e.g., with two infrared emitters and receivers, are used to retain the knowledge of the precise location of the surgical incision site. In total, a modification of the benchmarks for coordinates is necessary in this for the surgical incision site. For the implementation of this modification, a means of reference somehow shaped geometrically in a suitable manner identifiable from the second measurement system (called navigation system in the following) is fixed mostly in the area of the surgical incision at the operating table or another location in the operating room with a permanent reference to the surgical incision. The second measurement system (navigation system) for this does not necessarily have to be different from the first measurement system.

Thus in the meantime, 2- or 3-dimensional navigation systems, for example, are often used with the corresponding number of, e.g. infrared emitters and receivers which comprise a means of reference, e.g. in the form of a three-armed star (called a navigation basis unit).

By moving the pictures of the incision site produced by the first and second measurement systems "one above the other", e.g. on a suitable monitor, the modification of the benchmarks for coordinates is then performed. In order not to lose

the reference of the position of the incision site during the operation to the position of the incision site during the first, usually more precise measurement, it is therefore necessary for the navigation system, during the operation as well, to interact more or less permanently with the means of reference, so that the means of reference should be fixed, if possible, outside of the area of the surgeons' movements as possible. On the other hand, the means of reference are to be fixed advantageously near the incision site.

10 As a compromise, the necessity results then, apart from the incision site, to also cover the means of reference in a as sterile as possible manner but to remain identifiable for the navigation system. This task is made more difficult in the cases where the means of reference - for reasons of work ergonomics for the operating team - is fixed at a level which is outside of the work area of the operating team and with that usually above the incision site.

In the state of the art, in particular from the aforementioned publications, there is no feasible solution known for that. In the state of the art there are only such surgical drapes known which feature, apart from a fenestration for an incise film, another - attached to one side of the drape - fluid-impervious pouch in the area between the upper border of the incise film and the upper end of the drape. Furthermore known drapes usually still feature a means of tensioning on the lateral borders of the incise film and in the area of entry of the fluid-impervious pouch. Usually these means of tensioning, e.g. in the form of metal strips, serve as a guide for fluids or surgical residues, so that all of these come to be in the pouch.

[Tasks of the invention]

It is, therefore, the task of the invention to provide a novel surgical drape which apart from enabling sterile cover
5 of the surgical incision site, also enables sterile cover for means of reference shaped somehow for known measurement systems, in particular measurement systems using infrared radiation.

10 **[Practical embodiments]**

This task is solved by the subject matter of patent claim 1.

This problem is solved with a surgical drape with a first fenestration for an incise film with or without a collection
15 pouch related to that film for surgical residues according to the state of the art, characterized by the fact that the drape features at least one further fenestration for the reception of a means of cover for a means of reference protruding from the level of the drape's surface which is
20 identifiable for a 2- or 3-dimensional measurement system.

With that, the advantage of also sterilely covering a means of reference next to the patient, something that is common for modern - equipped with 2- or 3-dimensional measurement
25 devices - operating rooms, is achieved without limiting the mobility of the means of reference or having to break the border between the sterile and non-sterile operating area during the operation.

The entire novel drape can, therefore, be sterilized in one
30 go. With that a significant gain in time results for the preparation of the operation as well, which can, for example, be dedicated to the patient.

Further advantages result from the subject matter of the respective subclaims, or the production methods claimed.

Further details and advantageous realizations of the invention result from the practical embodiments described in the following and depicted in the figures, as well as from the subclaims below. It shows:

Fig. 1 a cross-section of the drape according to the present invention along the line I-II from Fig. 2

Fig. 2 a view from above of the drape according to the present invention with two means of cover

Fig. 3 a cross-section of a means of cover according to the present invention

Fig. 4a a cross-section of an embodiment of the means of cover according to the present invention

Fig. 4b a cross-section of a further embodiment of the means of cover according to the present invention

Fig. 1 shows an embodiment of the means of cover according to the present invention in a cross-section of the line I-II from Fig. 2. In this, the means of reference 4 covered by the means of cover 3, which is bound with the drape 1 at the perimeter of a second fenestration (2'), is depicted. In the left part of the figure, the first fenestration 2 for the incise film 8 is depicted. Above that, in the direction of the border of the drape 1 is depicted the fluid collection pouch 9 related to the incise film.

Fig. 2 shows a view from above of the drape according to the present invention, in this embodiment with two means of cover, which measure approx. 25 cm in diameter respectively and are arranged approx. 50 cm away from the center of the incise film. Through this, swinging the means of reference to the other side of the operating table is easily performable even during an operation.

Likewise the incise film 8 is depicted as well as the fluid collection pouch 9.

Fig. 3 shows a cross-section of a further advantageous embodiment of the means of cover 3, depicted with the means of reference 3 in the form of a three-armed indicator, which is fastened to a holder 4a. A non-transparent part 3b is bound to the upper part 3a which is transparent for the known measurement systems. This can be produced, e.g. from stiffer and/or tougher material than the upper part, so that the entire means of cover 3 stands more or less on its own, without support, on a holder.

On the left side, a means of reduction 7a is depicted with which the perimeter of the means of cover can be reduced vertically to the longitudinal axis. In this embodiment, i.e. only as an example, a strip with an adhesive element is provided for this.

For shortening the means of cover, a means of shortening 7b, depicted on the right side of the figure, is provided, which is likewise equipped with adhesive elements 10. Thus, the means of cover can be adjusted to the means of reference and its position in a simple manner (e.g. variable by a moveable holder), avoiding unnecessary creases to distort the radiation coming from the measurement system by the means of cover or the reflected radiation from the means of reference (e.g. by scattering, etc.).

Fig. 4a shows the means of cover 3 in a form (round points) which has been adjusted to the form of the means of reference by the means of reduction 7a.

This adjustment can also occur by pre-shaping of the means of cover, whereto the upper end of the means of cover features corresponding shapes.

Fig. 4b shows a further advantageous embodiment of the means of cover 3, whereby this time a flat end ensures a good

fit with the means of reference formed in this case by a three-armed star with balls as reference points.

A particularly preferred embodiment is given in that the means of cover is designed with elastic or plastic transparent materials, whereby the means of cover features simultaneously the capacity to be inflated. Therewith, any formation of creases, etc. is prevented. For this purpose, the bottom end on the means of cover is manufactured to be closed and features a valve on the surface and, if necessary, means of pumping.

It is immediately obvious that the means of cover must not necessarily be manufactured elongated or in the form of a cylinder with one or two closed ends. Every other form can likewise contribute to the desired sterile coverage of a means of reference.

Hereby, means of reference is understood to be any means which, through the known measurement or navigation systems in the running of a hospital, is suitable to mark a point in a 2- or 3-dimensional space or to relate with that a coordinate point of reference.

[List of reference numerals]

	Drape	1
5	Fenestration	2, 2', 2'', 2'''
	Means of cover	3
	Means of cover, transparent area	3a
	Means of cover, non-transparent area	3b
10	Means of reference	4
	Holder for means of reference	4b
	Surgical incision site	5
15	Measurement system, navigation system	6
	Means of reduction	7a
	Means of shortening	7b
20	Incise film	8
	Fluid collection pouch	9
	Adhesive element	10
25	Valve	11
	Means of pumping	12